

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**PACIRA PHARMACEUTICALS, INC.,
and PACIRA BIOSCIENCES, INC.,**

Plaintiffs,

v.

**eVenus PHARMACEUTICALS
LABORATORIES, INC., JIANGSU
HENGRUI PHARMACEUTICALS CO.,
LTD., and FRESENIUS KABI USA, LLC,**

Defendants.

**Civil Action No. 22-00718
Civil Action No. 21-19829
(Consolidated)**

OPINION

ARLEO, UNITED STATES DISTRICT JUDGE

THIS MATTER comes before the Court by way of a joint application for claim construction pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), presented by Plaintiffs Pacira Pharmaceuticals, Inc. and Pacira Biosciences, Inc. (“Plaintiffs” or “Patentees”) and Defendants eVenus Pharmaceuticals Laboratories, Inc., Jiangsu Hengrui Pharmaceuticals Co., Ltd., and Fresenius Kabi USA, LLC (collectively, “Defendants”).¹ This Opinion contains the Court’s construction of patent terms disputed by the Parties.

I. BACKGROUND

This consolidated action arises from Defendants’ alleged infringement of two patents owned by Plaintiffs related to Exparel, an FDA-approved non-opioid analgesic used to relieve postsurgical pain. Exparel is an injectable formulation of bupivacaine, a numbing agent,

¹ Defendant eVenus is a wholly owned subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd. See Corporate Disclosure Statement, ECF No. 13. According to Plaintiffs’ Complaint, “Jiangsu Hengrui will manufacture the active pharmaceutical ingredient (“API”) for the eVenus ANDA Product.” Compl. ¶¶ 5-6.

encapsulated in multivesicular liposomes (“MVLs”). Pacira has held several patents for Exparel, all part of the same “family” as the disputed patents here, five of which have since expired.²

Pacira developed Exparel as a safer alternative to opioids for postsurgical pain relief.³ Declaration of Alexander M. Klibanov, Ph.D. (“Klibanov Dec.”) ¶¶ 29-30, ECF No. 99-20; see also Pl. Ex. 4, NIH Prescription Opioids DrugFacts at 1-3. The FDA first approved Exparel in 2011 for “local administration to provide post-surgical analgesia,” and in 2018 for the expanded “use in interscalene brachial plexus nerve block for post-surgical analgesia for shoulder surgery.” Pl. Ex. 5, FDA Exparel Press Release at 2. In 2021, the FDA approved Pacira’s supplemental new drug application (sNDA) for Exparel’s use in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia.” Pl. Ex. 6, Pacira Press Release at 1.

Exparel is composed of multivesicular liposomes (“MVLs”). A liposome “is a microscopic structure consisting of a phospholipid bilayer encapsulating an aqueous core.” Pl. Ex. 3, Journal of Pain Research, at 258. Due to their hydrophilic and hydrophobic properties and biodegradability, liposomes are often used as drug delivery systems for a wide variety of drug products. Def. Ex. 25, Declaration of Alpaslan Yaman, Ph.D. (“Yaman Dec.”) at ¶¶ 22–23, 25–26. As relevant here, a multivesicular liposome (MVL) is a type of liposome in which one vesicle contains one or more smaller nonconcentric compartments, or vesicles, each separated by lipid

² Those include U.S. Patent Nos.: 6,132,766 (expired November 16, 2013); 8,182,835 (expired September 18, 2018); 8,834,921 (expired September 18, 2018); 9,205,052 (expired September 18, 2018); and 9,585,838 (expired December 24, 2021). See Def. Exs. 18-22 (Feb. 2012 – Mar. 2017 FDA Orange Book Supplements). Other patents in the same family that have not yet expired include U.S. Patent No. 11,426,348 (“‘348 Patent”); 11,278,494 (“‘493 Patent”); and 11,357,727 (“‘727 Patent”). See Def Exs. 4-5.

³ Pain is traditionally managed using opioids, but opioids have become disfavored due to their negative side effects and potential for addiction. Opioids are systemic, and affect the entire body, and can have various unpleasant side effects, including nausea, vomiting, and respiratory depression. Klibanov Dec. ¶ 29; Pl. Ex. 18, Exparel Website, at 1. In addition to temporary side effects, however, their long-term use can lead to dependence and addiction that can be life-threatening, which has fueled the devastating opioid epidemic in the United States and worldwide. Pl. Ex. 18 at 1; Pl. Ex. 6 at 1; Klibanov Dec. ¶¶ 41-42.

bilayers. Klibanov Dec. ¶ 3; Yaman Dec. at ¶ 24. Described differently, “[e]ach particle is composed of a honeycomb like structure of numerous internal aqueous chambers containing encapsulated bupivacaine.” Pl. Ex. 3 at 258. That structure allows for increased stability and sustained release of the drug from the vesicles, as a breach in the external layer of the MVL causes a release of the drug from only the first layer of vesicles, and redistribution of the drug within the inner vesicles without release. Id.; Klibanov Dec. ¶¶ 33-34. By nature of its MVL structure, Exparel is a long-acting formulation that “increases the duration of local anesthetic action.” Pl. Ex. 3 at 257. Exparel is a targeted injection “working directly at the surgical site.” See Pl. Ex. 18, Non-Opioid Pain Medication, Exparel Website at 1.

In the years after Exparel’s 2011 FDA approval, Pacira upscaled its manufacturing process to develop the drug in larger quantities. The patents at issue here, the 11,033,495 patent (the “‘495 Patent”) and the 11,179,336 patent (the “‘336 Patent”), are both titled “Manufacturing of Bupivacaine Multivesicular Liposomes,” and were developed to address the growing demand for Exparel “given the addictive nature of opioids and the opioid epidemic that has been affecting countries around the world.” Pl. Ex. 1 (“‘495 Patent”) at 1:32-26; Pl. Ex. 2 (“‘336 patent”) at 1:39-43. Both patents inform that the product is made by a scaled-up batch manufacturing process⁴ that “yield[s] a more stabilized form of bupivacaine encapsulated MVLs.” ‘495 Patent at 4:37-38; ‘336 Patent at 4:43-44. Scaling up the manufacturing process is more nuanced than simply increasing the raw materials and using larger equipment, Klibanov Dec ¶ 37, and it is “not a matter of simply

⁴ A “batch process” is a manufacturing method where “the raw material is charged into the system at the beginning of the process, and the product is discharged all at once sometimes later. No ingredients cross the system boundaries between the time the raw material(s) is charged and the time the product is discharged.” Pl. Ex. 9 (“Lee Article”) at 1. This is distinct from a “continuous process,” another drug manufacturing method, where “the material(s) and product are continuously charged into and discharged from the system, respectively, throughout the duration of the process.” Id. at 2.

adding more material or getting a bigger piece of equipment,” Markman Tr. at 9:5-7.⁵ The patents indicate that the larger batch process produced “unexpected” improvement in the drug’s physical properties, as compared to the commercial version of Exparel from prior patents. ‘495 Patent at 13:49-59.

Defendant eVenus filed an Abbreviated New Drug Application (“ANDA”) pursuant to 21 U.S.C. § 355(j) seeking approval to manufacture generic versions of Exparel prior to the expiration of the ‘495 patent, pursuant to 21 U.S.C. § 355(j). Compl. ¶ 38, ECF No. 1. Plaintiffs thereafter initiated this action against Defendants on November 8, 2021 through a Complaint alleging infringement of the ‘495 and ‘336 Patents. See generally Compl., ECF No. 1. The Parties exchanged opening Markman briefs on October 28, 2022, ECF Nos. 99, 100, and responsive briefs on December 15, 2022, ECF Nos. 109, 110. The Court conducted a claim construction hearing on March 9, 2023. This Opinion follows.

II. LEGAL STANDARD

A patent claim is that “portion of the patent document that defines the scope of the patentee's rights.” Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 321 (2015). When the parties in a patent infringement action “present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it,” O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1362 (Fed. Cir. 2008), and the meaning and scope of patent claims are questions of law to be decided by the Court. Markman, 517 U.S. at 372.

A court “first look[s] to the actual words of the claims and then read[s] them in view of the specification.” Profectus Tech. LLC v. Huawei Techs. Co., 823 F.3d 1375, 1380 (Fed. Cir. 2016). “The words of a claim are generally given their ordinary and customary meaning,” which is “the

⁵ References to Markman Transcript refer to the Markman Hearing the Court held on March 9, 2023. See ECF No. 161.

meaning that the term would have to a person of ordinary skill in the art [POSA] in question at the time of the invention.” Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (citation and quotation marks omitted). There are two exceptions to that rule: “1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution.” Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). A patentee acts as lexicographer where it “clearly set[s] forth a definition of the disputed claim term,” and “clearly express[es] an intent to define the term.” Id. (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002) and then quoting Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008)).

To ascertain a term’s meaning, the Court looks first to “intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent.” Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc., 731 F.3d 1271, 1276 (Fed. Cir. 2013). In particular, a patent’s specification is considered the “single best guide to the meaning of a disputed term,” and “[u]sually, it is dispositive.” Phillips, 415 F.3d at 1315 (citation and quotation marks omitted). The patent’s prosecution history “consists of complete record of proceedings before [the] PTO [Patent and Trademark Office] and includes prior art cited during examination of patent.” Id. at 1317.

While “less significant” than the intrinsic record, the Court may also rely on “extrinsic evidence,” i.e., “all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” Id. (citation and quotation marks omitted). For example, the Federal Circuit has specifically endorsed the use of technical dictionaries to permit a court “to better understand the underlying technology and the way in which one of skill

in the art might use the claim terms.” Id. at 1318 (citation and quotation marks omitted). But extrinsic evidence may not be used to “vary” or “contradict” the terms of a claim, and it should be discounted where “clearly at odds with the [intrinsic evidence].” Key Pharms. v. Hercon Lab’ys Corp., 161 F.3d 709, 716 (Fed. Cir. 1998).

III. ANALYSIS

The parties request construction of: 1) the preamble of claim 1 of the ‘495 patent, 2) the preamble of claim 1 of the ‘336 patent, 3) the shear speed terms of both patents, and 4) the pH terms of both patents.⁶ The Court addresses each in turn, after a careful review of the parties’ claim construction briefs, including the declarations and exhibits, the technology tutorials submitted by both parties, argument during the Markman hearing, and all applicable statutory and case law.

A. Preamble of Claim 1 of the ‘495 Patent

As to the preamble of claim 1 of the ‘495 Patent, the parties have proposed the following for construction:

<u>Disputed Term</u>	<u>Plaintiffs’ Construction</u>	<u>Defendants’ Construction</u>
“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs) prepared by a commercial scale process” (Proposed by Plaintiff) ‘495 patent, claims 1-22	Pacira proposes that the preamble as a whole is limiting and should be construed to mean: “An aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs) having a batch volume greater than about 45 liters to about 250 liters prepared by a process”	Defendants dispute that it is appropriate to construe the full preamble and have proposed to construe certain smaller terms from the preamble.

⁶ The parties group the disputed claims differently. Plaintiff requests different constructions for the preamble of claim 1 of both the ‘495 patent and the ‘336 patent. Because of the similar language in both preambles, however, Defendants request construction of only the three smaller phrases within the ‘495 patent. The Court will follow Plaintiffs’ breakdown of the disputed terms, as laid out here, and will address Defendants’ proposed constructions as part of the preambles for claim 1 of the ‘495 and claim 1 of the ‘336 patent.

“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” (Proposed by Defendants) ‘495 patent, claims 1-22	Addressed above as part of the full preamble.	“a multivesicular liposome composition encapsulating bupivacaine”
“commercial scale” (Proposed by Defendants) ‘495 patent, claims 1-22	Addressed above as part of the full preamble.	“a scale of manufacturing for production of a commercial product”
“prepared by a commercial scale process” (Proposed by Defendants) ‘495 patent, claims 1-22	Addressed above as part of the full preamble. Pacira disputes that “prepared by a commercial scale process” is a product-by-process limitation to the extent the scale informs the claimed “composition.”	Defendants contend that this term should be construed as a product-by-process claim limitation as part of claim construction.

The parties dispute whether the preamble of claim 1 of the ‘495 patent should be construed in full, such that “commercial scale” informs the meaning of the claimed “composition,” or in smaller parts.⁷ Plaintiffs argue the preamble as a whole should be construed narrowly to read: “An aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs) having a batch volume greater than about 45 liters to about 250 liters prepared by a process.” Pl. Opening Br. at 11-22. Plaintiffs maintain that the 45-liter minimum is informed by the batch volume of the existing commercial process, from which Pacira scaled up. *Id.* at 12-22. Defendants argue this more limited definition is proposed only to avoid a finding of invalidity, and the Court should instead construe “a multivesicular liposome composition encapsulating bupivacaine” as “a composition of bupivacaine encapsulated multivesicular liposomes (MVLs)[,]” as the

⁷ The parties originally disputed whether the preamble of the ‘495 Patent is limiting, but at oral argument, the parties informed the Court that they agree the preamble of the ‘495 patent is limiting. See *Markman* Tr. 5:16-23.

specification provides. Def. Opening Br. at 2-7. Defendants also argue the term “commercial scale” should be construed as “a scale of manufacturing for production of a commercial product.” Id. at 14-22. The Court agrees with Defendants.

First, “a claim preamble has the import that the claim as a whole suggests for it.” Bell Comms. Rsch, Inc. v. Vitalink Comms. Corp., 55 F.3d 615, 620 (Fed. Cir. 1995). “If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (quoting Kropa v. Robie, 187 F.2d 150, 152 (CCPA 1951)). “[W]hen discussing the ‘claim’ in such a circumstance, there is no meaningful distinction to be drawn between the claim preamble and the rest of the claim, for only together do they comprise the ‘claim.’” Id. Against this background, the Court analyzes the preamble in turn, specifically with respect to the terms “composition” and “commercial scale.”

i. “Composition”

The Court first looks to intrinsic evidence to construe the preamble language, which begins with the claim language itself. See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed. Cir. 2004) (“Claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’”). (quoting Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001) (alterations in original)).

Here, the claim language makes clear that the preamble’s use of the term “composition” refers to several forms of bupivacaine encapsulated MVLs. Claim 1 sets forth that the invention

must “first” be in the form of an aqueous suspension, but throughout the steps, that solution is transformed to a “water-in-oil” emulsion, forms a “second aqueous suspension,” and ultimately a “third aqueous suspension.” See ‘495 Patent at 22:46-23:5.

While the parties do not dispute the meaning of the term composition, the Court notes that Defendant’s proposed construction is consistent with the plain and ordinary meaning of “composition.” The Federal Circuit has held that “[a] technical term in a patent document has the meaning that it would be understood to have by persons knowledgeable in the field of the invention and the prior art.” Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1326 (Fed. Cir. 2004). Such a term, however, “is not properly removed from its context in order to seek its meaning.” Id. With that in mind, a chemical “composition” is well-established as a term of art in both chemistry and patent law to be a mixture of substances, not simply the ingredients before they are mixed. See PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235, 1244 (Fed. Cir. 2002) (“Although the construction of a term in a patent claim is a highly contextual exercise that is dependent upon the content of the particular patent in which the term appears . . . , the basic definition of the term ‘composition’ is well-established.”). In Exxon Chemical Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1558 (Fed. Cir. 1995), the Federal Circuit explained that “[t]he chemical composition exists at the moment the ingredients are mixed together. Before creation of the mixture, the ingredients exist independently.” According to the Federal Circuit, the term “composition” does not have a temporal limitation; rather, a composition can exist at any time during a preparation or manufacturing process. Id.

Here, the parties have agreed that the preamble of claim 1 of the ‘495 patent is limiting, and dependent claims 2-3, 5, 7, 9, 13, and 17-20 refer to, and modify, the “composition.” See Markman Tr. at 5:16-6:3. Given that the “composition” term supplies necessary structure to claim

1, and serves as an antecedent for the dependent claims, the Court will decline Plaintiffs’ invitation to limit it to an “aqueous suspension.” See INVISTA N. Am. S.a.r.l. v. M & G USA Corp., 951 F. Supp. 2d 604, 611-14 (D. Del. 2013) (analyzing the Federal Circuit’s treatment of the term “composition” and rejecting the defendant’s proposed limitation of the term).

The specification also offers guidance as to the first phrase of the preamble. Here, Plaintiff has defined “the terms ‘bupivacaine encapsulated multivesicular liposomes,’ ‘bupivacaine-MVLs’ or ‘bupivacaine MVLs’” to mean “a multivesicular liposome composition encapsulating bupivacaine.” ‘495 Patent at 4:47-50; Novartis Corp. v. Teva Pharms. USA, Inc., 565 F. Supp. 2d 595, 608–09 (D.N.J. 2008) (“The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.”) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Defendants therefore construe the first portion of the preamble – “a composition of bupivacaine encapsulated multivesicular liposomes” – as “a multivesicular liposome composition encapsulating bupivacaine” by applying the definition provided in the specification. Def. Opening Br. at 7-9. Plaintiffs argue that this proposed construction “is not helpful and is hardly a construction at all as it merely removes the acronym MVL and rearranges the words in the claim language.” Pl. Opening Br. at 12.

Plaintiffs, however, fail to provide a compelling reason for departing from the definition provided in the specification, such that “a composition of bupivacaine encapsulated multivesicular liposomes” is narrowed to “an aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs).” Indeed, the specification explicitly states that the embodiment of the composition is not restricted to an aqueous suspension. The ‘495 Patent explains that “in any embodiments of the composition of bupivacaine encapsulated MVLs described herein, the composition may be a pharmaceutical composition suitable for human administration.” ‘495

Patent at 20:13-16. In further embodiments, “the composition may be an aqueous suspension of bupivacaine encapsulated MVL particles.” Id. at 20:16-18. The Federal Circuit has “cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.” Lemelson v. United States, 752 F.2d 1538, 1552 (Fed. Cir. 1985) (citing Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1568 (Fed. Cir. 1983)). The specification also describes the prior art as bupivacaine MVL “compositions,” rather than “aqueous suspensions.” See ‘495 Patent at 4:7-24 (comparing the claimed art to the “bupivacaine MVL compositions prepared by the existing commercial manufacturing process”).

The prosecution history also informs that the prior art referred to in the ‘495 Patent⁸ is described as a “composition,” not as an aqueous suspension. In fact, Pacira’s ‘838 Patent, which is incorporated by reference in the ‘495 Patent, see ‘495 Patent at 4:31–45, claims “[a] process for preparing a multivesicular liposomal particle composition” in its preamble to claim 1. See Def. Ex. 3, ‘838 Patent 4:20-24. As such, the Court is satisfied the composition can be any form of matter containing bupivacaine MVLs, and will construe the preamble as defined in the specification: “a composition of bupivacaine encapsulated multivesicular liposomes (MVLs).”

ii. Commercial Scale

As to the term “commercial scale process,” Plaintiffs propose that it should be construed as part of the whole preamble: “an aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs) having a batch volume greater than about 45 liters to about 250 liters prepared by a process.” Pl. Opening at 20-22. Plaintiffs aver that the 45-liter minimum comports with the volume associated with prior art, and that the 250 liters represents the new, larger scale. Id. at 16-20. Defendants, on the other hand, contend that the phrase should be construed in isolation as “a

⁸ Plaintiff also confirms that the prior art the 495 Patent refers to is the ‘838 Patent. Pl. Opening Br. at n.4

scale of manufacturing for a production of a commercial product.” Def. Opening Br. at 33-37. The Court agrees with Defendants.

First, the body of the claim does not specify any volume limitation. See generally ‘495 Patent at 22:42-23:13. Claim 1 refers generally to “reducing the volume” of the composition as part of the process, but does not impose any specific minimum or maximum limit. See ‘495 Patent at 22:64-65; 23:2-3. In its brief, and at the Markman hearing, Plaintiff acknowledges that “[t]he specification . . . does not explicitly specify a numerical value for the batch volume of Pacira’s existing process.” Pl. Opening Br. at 18; see also Markman Tr. 20:10-16 (counsel for Plaintiff noting “that the patent doesn't specifically state what [the] batch volume was of the current process”).

While the specification articulates various volumes as examples, the claimed invention should not be limited “to [those] specific examples in the specification.” Lemelson, 752 F.2d at 1552 (citing Fromson, 720 F.2d at 1568). The specification includes several exemplary embodiments where the volume of the claimed art ranges from 10 milliliters to 250 liters. See, e.g., ‘495 Patent at 17:26-33 (“In some embodiments of the composition described herein, the composition of bupivacaine encapsulated multivesicular liposomes may have a final volume of about 150 L to about 250 L, or about 200 L to about 250 L, before being filled into individual containers for human administration. In other embodiments, the composition of bupivacaine encapsulated MVLs may have a volume of 10 mL or 20 mL for a single dose administration.”); id. at 12:42-49 (“In one embodiment, the final aqueous suspension of bupivacaine encapsulated multivesicular liposomes has a volume of about 200 L. In another embodiment, the final aqueous suspension of bupivacaine encapsulated multivesicular liposomes has a volume of about 225 L.”). The smallest volume the examples propose is 150 liters, and the specification does not indicate

anywhere that the minimum volume produced by the commercial scale process must be 45 liters. See ‘495 Patent at 12:42-49; 16:26-33.

The specification further notes that “[t]he newly developed processes provide up to 5 folds increase in final product volume as compared to the current process used for the manufacturing of Exparel[], which is disclosed in U.S. Pat. No. 9,585,838 and is incorporated by reference in its entirety.” Id. at 4:31-35. That patent – the ‘838 patent – defines “commercial scale” as distinct from a smaller “lab scale” or “bench scale.” The ‘838 specification states that “‘commercial scale’ refers to preparation of product in quantities or batches greater than or approximately equal to about a liter (or about 0.1 L for proteinaceous preparations) up to 100 L, for example 1, 10, 25 or 75 L.” See ‘838 Patent, Ex. 3 at 5:10-24. By contrast, the ‘838 specification defines “laboratory scale”, “lab scale”, or “bench scale” as “reactions and processes of scales less than about a liter, such as 0.025 L, or 0.2 L.” Id.⁹ The lack of an express definition for “commercial scale” in the ‘495 Patent, on the other hand, indicates to the Court that the plain and ordinary meaning of the term should be used, rather than reading into the term a volume limitation.

In addition, the specification describes the prior art as produced by a “commercial process” or a “commercial manufacturing process.” ‘495 Patent at 16:30-35 (comparing the lysine concentration of the claimed art to that of the “current commercial process”); id. at 16:50-56 (comparing the dextrose concentration of the claimed art to that of the “current commercial process”); id. at 4:13-24 (describing Figures 3B and 3C as comparisons to the “to bupivacaine-MVL compositions prepared by the existing commercial manufacturing process”); see also id. at

⁹ This distinction is explained by Defendant’s expert, Dr. Yaman, in his Declaration. According to Dr. Yaman, a POSA would understand that “[t]herapeutic products are typically first developed at smaller scales, referred to colloquially as “benchtop” or “laboratory” scales, as they typically involve processes that are performed with equipment on a benchtop in a laboratory.” Yaman Dec. ¶40. Those processes are “generally not suitable to make an amount necessary for a commercial product,” and therefore are “scaled up” to a larger “commercial scale.” Id.

20:33-38; 21:24-33. Again, without any express definition of the “commercial manufacturing process” to which Plaintiffs refer, the term should take its ordinary meaning to avoid inconsistent constructions throughout the specification (i.e. the prior “commercial manufacturing process refers only to volumes up to 45 liters, and the new “commercial manufacturing process” refers to volumes of 45 to 250 liters).

Plaintiffs argue, however, that the Court must look to extrinsic evidence to construe the lower limit of 45 liters. Plaintiffs rely on Road Science, LLC v. Telfer Oil Co. for the proposition that “in order to properly construe the disputed term, the court still must look to extrinsic evidence because the specification explicitly references prior art to define [the term], but does not provide further clarification.” No. 10-cv-0786, 2012 WL 1739817, at *6 (E.D. Cal. May 15, 2012). Indeed, where “analysis of the intrinsic evidence will not resolve an ambiguity in a disputed term or phrase,” extrinsic evidence, in the form of ““expert and inventor testimony, dictionaries, and learned treatises,”” Phillips, 415 F.3d at 1317 (quoting Markman, 52 F.3d at 980), “may be accepted by the court to enhance its understanding of the technology.” Gart v. Logitech, Inc., 254 F.3d 1334, 1340 (Fed. Cir. 2001). “However, extrinsic evidence cannot be used to contradict the established meaning of the claim language.” Id. (citations omitted).

Plaintiffs maintain that the 45-liter scale was “public knowledge,” Pl. Opening Br. at 19, and that Product Facilities Group, LLC, a company that supported Pacira’s scale-up manufacturing process, confirmed that Pacira’s existing process was a batch process that produced “45 liters of Exparel.” See Pl. Ex. 12 at 4 (Product Facilities Group Website). Plaintiffs also point to various earnings calls, in which its CEO confirmed the prior process was at a 45-liter scale, which would be increased to a 200-liter scale. See Pl. Ex. 13 at PAC-EXPAREL00796825 (Transcript of August 2, 2018 Earnings Call).

Plaintiffs’ expert Dr. Klibanov also suggests that a POSA would understand that the term commercial scale implicates a lower volume limit of 45 liters, and an upper limit of 250 L. In support, he states that a POSA would look to both intrinsic and extrinsic evidence to inform this range. Klibanov Dec. ¶¶ 52-59. He cites to the declaration from Kathleen Los, one of the named inventors on the patent, who represented that the new manufacturing process would produce up to 200 liters. See Pl. Ex. 11, Kathleen Los Declaration (“Los Dec.”) at PAC-EXPAREL00796569. According to Dr. Klibanov, a POSA would understand from the ‘495 specification, however, that the upper limit is 250 liters (not 200 liters as Dr. Los informs) because the specification “repeatedly describes the volume produced by the ‘commercial scale process’ as up to ‘about 250 liters.’” Klibanov Dec. ¶ 55 (quoting ‘495 patent at 12:42-45; 17:26-29).

Dr. Klibanov also opines that a POSA would turn to further extrinsic evidence to obtain the lower limit of 45 liters, and more specifically to Plaintiffs’ 2016 website, wherein, as discussed above, “the Product Facilities Group, LLC (a group that . . . provided support for Pacira’s manufacturing facilities), distinguished a spray process used to produce 16 liters of EXPAREL® from the batch manufacturing process “that generates 45 liters of EXPAREL.” Id. ¶ 57 (citing Pl. Ex. 12 at PAC-EXPAREL00796836). Dr. Klibanov also suggests that a POSA should look to “statements made by Pacira’s executives during publicly held corporate earnings calls” for the 45-liter lower limit, including “a 2019 earnings conference call,” in which “Pacira’s Chief Financial Officer explained that Pacira used “45-liter batch process.” Id. ¶ 58.

The Court is not convinced that this extrinsic evidence compels Plaintiffs’ proposed construction. “In divining a claim's meaning, a court must give more weight, perhaps even dispositive weight, to intrinsic evidence—which includes inferences drawn from the full context of the patent, the specifications, and the prosecution history—rather than to extrinsic evidence.”

Amgen, Inc. v. F. Hoffmann-La Roche Ltd., 494 F. Supp. 2d 54, 61 (D. Mass. 2007). As such, the court relies on the extrinsic evidence highlighted by Plaintiffs and Dr. Klivanov with “some degree of caution,” id. at 62, and instead prioritizes the body of the claim and the specification of the ‘495 Patent, which make no suggestion to any volume limitation. Rather, as noted, the intrinsic record suggests that the volume’s lower limit would be 150 liters, and supports several definitions of the term “commercial scale.” As such, “the term may be construed to encompass all such consistent meanings.” See Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1343 (Fed. Cir. 2001).¹⁰

Accordingly, the Court will not limit the term “commercial scale” to the range of 45 liters to 250 liters. It is clear from the specification that the claimed art is “new and improved large scale production” of the existing manufacturing process, and the scale-up of the existing manufacturing process was intended to address the “growing demand” for Exparel “given the addictive nature of opioids and the opioid epidemic.” See ‘495 Patent at 1:15-36; ‘336 patent at 1:39-43. Accordingly, any volume limitation – particularly one with an upper limit – would be inconsistent with Plaintiffs’ goal of increasing the global supply of Exparel. See Markman Tr. at 8:5-12 (counsel for Plaintiffs explaining that there “became a high need and demand for better pain management, nonopioid dependent pain management. And that is why there was really a cry to have an increased amount of Exparel available. And so to do that, you have to scale up your manufacturing processes . . . you have to be able to produce it on a bigger scale”).

In short, there is no basis to depart from Plaintiffs’ express definition of “a composition of bupivacaine MVLs” or to impose a volume limitation on the term “commercial scale.” The Court adopts the following construction for the preamble of the ‘495 Preamble:

¹⁰ Neither have Plaintiffs disavowed the full scope of the claim term during prosecution. See generally, Pl. Ex. 10, ‘495 File History, PAC-EXPAREL00000459-00002638.

<u>Disputed Term</u>	<u>Adopted Construction</u>
“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” ‘495 patent, claims 1-22	“a multivesicular liposome composition encapsulating bupivacaine”
“commercial scale” ‘495 patent, claims 1-22	“a scale of manufacturing for production of a commercial product”

B. Product-by-Process Dispute

As part of claim construction, the Court must also determine whether the disputed “commercial scale” term of the preamble to the ‘495 Patent is a product-by-process limitation. Plaintiffs do not dispute that claim 1 is a product-by process claim, but argue that the “term “prepared by a commercial scale process” is not a product by process limitation within that claim, as it informs the structural properties of the claimed composition. See Pl. Opening Br. at 14-16. Defendants argue that the term is “a quintessential ‘product-by-process’ limitation.” Def. Opening Br. at 34-37.¹¹ The parties propose the following:

¹¹ Because the parties agree that the claim is a product-by-process claim, the process by which the product is made is covered by the patent. See Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1291-94 (Fed. Cir. 2009) (holding that product claims with process limitations are only infringed by products made by the claimed processes); see also Atl. Thermoplastics Co. v. Faytex Corp., 970 F.2d 834, 846-47 (Fed. Cir. 1992) (holding that the process steps do serve as claim limitations – a product made by a different process than that claimed in the patent’s product-by-process claim is not covered by the patent). The dispute surrounds whether the patent is construed to cover the product itself, and ultimately, if that product is patentably distinguishable from prior art. Medicines Co. v. Hospira, Inc., 827 F.3d 1363, 1374 (Fed. Cir. 2016) (“For validity purposes, the ‘invention’ . . . is the product.”).

Where a process imparts “structural and functional differences” distinguishing the prior art, such differences will be afforded patentable weight. Kamstrup A/S v. Axioma Metering UAB, 43 F.4th 1374, 1381 (Fed. Cir. 2022); In re Nordt, 881 F.3d at 1375; Amgen Inc. v. F. Hoffman-La Roche Ltd, 580 F.3d 1340, 1369-70 (Fed. Cir. 2009) (describing the different analyses of infringement and validity for product-by-process limitations); SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1316 (Fed. Cir. 2006) (discussing the history of product-by-process jurisprudence in the Federal Circuit and the Supreme Court). And “[i]f the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” MPEP § 2113 (8th ed., Rev. 2, May 2004) (quoting In re Thorpe, 777 F.2d at 698). Validity is not at issue at this stage, but the Court notes that the structure is what will ultimately determine that analysis, since the parties agree that the claim is a product-by-process claim.

<u>Disputed Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
“prepared by a commercial scale process” ‘495 patent, claims 1-22	Addressed above as part of the full preamble. Pacira disputes that “prepared by a commercial scale process” is a product-by-process limitation to the extent the scale informs the claimed “composition.”	Defendants contend that this term should be construed as a product-by-process claim limitation as part of claim construction.

Whether a term is a product-by-process limitation is part of the Court’s analysis at the claim construction stage. A “‘product-by-process’ . . . claim ‘is one in which the product is defined at least in part in terms of the method or process by which it is made.’” Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 159 n.* (1989) (quoting Donald S. Chisum, Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement § 8.05 (1988)). These types of claims typically “employ terms such as ‘prepared in accordance with,’ ‘by the process of,’ whereby, ‘product of the process,’ ‘resulting from the process of,’ and ‘being produced by the process comprising.’” Biacore AB v. Thermo Bioanalysis Corp., 79 F. Supp. 2d 422, 456 (D. Del. 1999), aff’d sub nom Biacore AB v. Thermo Bioanalysis Corp., 30 F.App’x 994 (Fed. Cir. 2002).

However, “[i]f the process limitation connotes specific structure and may be considered a structural limitation, . . . that structure should be considered.” In re Nordt Dev. Co., 881 F.3d 1371, 1374 (Fed. Cir. 2018). Indeed, “words of limitation that can connote with equal force a structural characteristic of the product or a process of manufacture are commonly and by default interpreted in their structural sense, unless the patentee has demonstrated otherwise.” Id. at 1375; see also First Quality Tissue, LLC v. Irving Consumers Prods. Ltd., No. 19-cv-428, 2020 WL 3542321, at *3-4 (recognizing that term “‘through air dried tissue’ is certainly a process” but rejecting the argument that it was a product-by-process limitation because it “connotes specific structure”).

Here, the Court agrees with Plaintiffs that the preamble is not a product-by-process limitation because it informs the structure and contains structural differences than the existing art. While the claim as a whole describes a process, intrinsic evidence demonstrates that the term connotes specific structure. The specification Patent at 4:26-40. More specifically, “the bupivacaine MVL particles produced by the process described herein have lower lipid hydrolysis byproducts compared to the commercial Exparel® product under the same incubation condition.” Id. The “higher internal lysine precisely explains what the structural limitation is, discussing the stability of the new product at length. It generally informs that the new process yields a “more stabilized form of bupivacaine encapsulated MVLs.” ‘495 and dextrose concentrations and more desirable internal pH . . . may improve MVL particle strength during product transportation, as well as lipid membrane stability.” ‘495 Patent 13:49-59; see also ‘495 Patent at 4:38-40 (stating that the “improved and scaled up process . . . ha[s] less lipid degradation byproducts, increased internal pH, and increased lysine and dextrose encapsulation.”). The specification also explains that “proper mixing rate is important . . . to the final product yield, the MVL particle stability and release properties.” ‘495 Patent at 7:64-67.

Further, during prosecution, the inventors distinguished their invention from prior art, noting that the larger scale manufacturing process produces a structurally different product than that made with the existing process. Pl. Ex. 10, ‘495 File History, at PAC-EXPAREL00002637; Pl. Ex. 11, ‘336 File History, at PAC-EXPAREL 00796569. And as noted by Plaintiffs’ expert, the “claim phrase ‘prepared by a commercial scale process’ in the preamble does not simply set out a process but, in fact, informs a POSA about the structural properties of the claimed ‘composition.’” Klibanov Dec. ¶ 66.

In addition, Defendants’ reliance on SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1316 (Fed. Cir. 2006) is misplaced. The Federal Circuit did not construe the claims in that matter, and the parties disputed whether the claim at issue was a product-by-process claim. SmithKline Beecham, 439 F.3d at 1314. Here, the parties disagree about whether the claim terms are a product-by-process limitation, and the specification makes abundantly clear that the product’s structure is ultimately informed by the process.¹²

The Court accordingly rejects Defendants’ proposal to construe “prepared by a commercial scale process” as a product-by-process limitation.

<u>Disputed Term</u>	<u>Adopted Construction</u>
“prepared by a commercial scale process” ‘495 patent, claims 1-22	“prepared by a commercial scale process” is not a product-by-process limitation

C. Preamble of Claim 1 of the ‘336 Patent

The parties propose the following constructions for the preamble to the ‘336 Patent:

<u>Disputed Term</u>	<u>Plaintiffs’ Proposed Construction</u>	<u>Defendants’ Proposed Construction</u>
“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” ‘336 patent, claims 1-20	Pacira proposes that the preamble as a whole is limiting and should be construed to mean: “An aqueous suspension of bupivacaine encapsulated multivesicular liposomes (MVLs) having batch-to-batch consistency”	“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” means “a multivesicular liposome composition encapsulating bupivacaine”

Similar to the preamble of the ‘495 Patent, Plaintiff argues that the preamble of the ‘336 Patent should be construed as a whole to mean “an aqueous suspension of bupivacaine

¹² The Court disagrees with Plaintiff that the ultimate product requires a specific volume range, however, as the language of the claim makes no mention of any required volumes. See supra, Section III.A.ii.

encapsulated multivesicular liposomes (MVLs) having batch-to-batch consistency.” See Pl. Opening Br. at 22-26. Because the ‘336 preamble arises in a different context than that of the ‘495 patent, Plaintiff proposes that the ‘336 preamble should be construed to specify an aqueous solution that has batch-to-batch consistency. Id. at 22-23. Defendants, however, contend that the preamble of claim 1 of the ‘336 Patent should be construed with the same definition as that of the ‘495 Patent, simply that “a composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” means “a multivesicular liposome composition encapsulating bupivacaine.” Def. Opening Br. at 10-14. Defendants propose that the disputed term should be construed “in alignment with the same definition” provided in Plaintiffs’ specification. Id. at 11. The Court agrees with Defendants.

Plaintiffs maintain that the same phrase that arises in different contexts will not necessarily be interpreted to have the same meaning. In re Jublia, No. 18-cv-13635, 2021 WL 100267, at *7 (D.N.J. Jan. 11, 2021) (“In claim construction, the same word or term used in different phrases will not necessarily be interpreted to have the same meaning, because these different phrases may represent different contexts for the same word or term, thereby attaching different connotations to it.” (citing Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1031 (Fed. Cir. 2002))). According to Plaintiff, because claim 1 of the ‘336 Patent is not a product-by-process claim like claim 1 of the ‘495 Patent, and because it does not reference a “commercial scale process,” the different contexts require different constructions. Pl. Opening Br. at 24. Plaintiff is correct that “context is important” as part of claim construction, Razor USA LLC v. DGL Grp., Ltd., No. 19-cv-12939, 2021 WL 651257, at *19 (D.N.J. Feb. 19, 2021), and “the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of [disputed] terms,” ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).

In order to account for the context in which certain terms appear, however, “the Court need not construe . . . long phrases.” Green Pet Shop Enters., LLC v. Comfort Revolution, LLC, No. 20-cv-2130, 2021 WL 5450185, at *4, n.4 (D.N.J. Nov. 19, 2021). And “individual terms, rather than lengthy phrases, should be construed.” *Id.* ; see, e.g., Integrated Prod. Servs. v. Prod. Control Servs., No. 11-1034, 2013 WL 4647316, at *11 n.9 (S.D. Tex. Apr. 17, 2013) (determining that the proposed phrase “downwardly facing cross-sectional area or surface area” should be construed as two separate terms, “downwardly facing cross-sectional area” and “surface area,” because “the including of the word ‘or’ in the phrase . . . made the phrase cumbersome and unclear”).

While different contexts may compel different meanings, the preamble of claim 1 of the ‘495 Patent and the preamble of claim 1 of the ‘336 Patent not only both include the term “[a] composition of bupivacaine encapsulated multivesicular liposomes (MVLs),” the patents also share a materially identical specification, several common claim terms, and originate from same parent application. ‘495 Patent at 22:43-44; ‘336 Patent at 22:43-44. When this is so, claim terms should be interpreted “consistently across all asserted patents.” SightSound Techs., LLC v. Apple Inc., 809 F.3d 1307, 1316–17 (Fed. Cir. 2015); see also Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1293 (Fed. Cir. 2005) (Where multiple patents “derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents.”).

Plaintiffs rely on cases where the Federal Circuit construed a term to have two different meanings when it appeared in two separate contexts. See Pl. Opening Br. at 23-25. In those cases, however, the term was not expressly defined in the specification as it is here. For example, in

Epcon Gas, “the term ‘substantially’ was used in two contexts with a subtle but significant difference” within the same patent 279 F.3d at 1031. Because the “phrase ‘substantially constant’ denote[d] language of approximation, while the phrase ‘substantially below’ significie[d] language of magnitude, i.e., not insubstantial,” the Court construed different meanings for each term. Id. And in In re Translogic Tech., Inc., 504 F.3d 1249, 1258 (Fed. Cir. 2007), the Federal Circuit explained that one claim of the disputed patent “had two similar, but significantly different phrases, ‘coupled to receive’ and ‘coupled to.’” Because the terms were “clearly different in the claimed . . . patent multiplexer circuit,” the Court construed each to have a different meaning. Id.

Here, however, the more accurate consideration is that “[a] word or phrase used consistently throughout a claim should be interpreted consistently.” Phonometrics, Inc. v. N. Telecom Inc., 133 F.3d 1459, 1465 (Fed. Cir. 1998). That rule applies under these circumstances, and the claim term “[a] composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” should be interpreted the same in the ‘495 and ‘336 patents. Indeed, both specifications expressly define the term as a “multivesicular liposome composition encapsulating bupivacaine.” ‘495 Patent at 4:47-50; ‘336 Patent at 4:53-56.

Further, for the same reasons discussed above, the Court will not read “aqueous suspension” into the ‘336 preamble. The specification makes clear that the composition, in some embodiments, “may be an aqueous suspension of bupivacaine encapsulated MVL particles.” ‘336 Patent at 20:18-23. The specification also notes, in the definitions section, that “in some embodiments, the composition is a pharmaceutical formulation, where the bupivacaine encapsulated multivesicular liposome particles are suspended in a liquid suspending medium form a suspension.” Id. at 8:56-60. As noted, the Federal Circuit has “cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification,” Lemelson,

752 F.2d at 1552, and the Court will not restrict the composition to an aqueous suspension in the absence of more precise guidance from Pacira that such an embodiment is the only viable embodiment for Claim 1.

Finally, the Court rejects Plaintiffs’ addition of “batch-to-batch consistency” as part of the preamble of claim 1 of the ‘336 Patent. Although Plaintiffs argue that the emphasis on stability “indicates to a POSA that the claimed composition has consistency in such properties across batches,” Pl. Opening Br. at 25, there is no suggestion in the body of the claim that batch-to-batch consistency is required. Indeed, Plaintiffs’ own arguments, as well as the ‘336 specification, indicate to the Court that the term “stability” refers to the measurement of the drug’s degradation over time, however, and not to stability across batches.

For example, Plaintiffs maintain that the stability achieved by the new process allows for “longer and more sustained release of the pain medicine over time.” Markman Tr. at 7:17-21.¹³ The examples in the specification also measure “stability” via the erucic acid concentration in the bupivacaine MVLs as a function of time,” as compared to the bupivacaine MVLs prepared by the current commercial process. ‘336 Patent at 30:34-49; Table 1A. Example 2 measures lysine and dextrose concentrations in bupivacaine MVLs, which revealed that the bupivacaine MVL particles prepared by the new process contained more lysine and dextrose, and the internal pH remained high, which contributed to stability over time. Id. at 21:61-22:41. And the Los Declaration, submitted as part of the ‘336 Patent application, states that “the new commercial process yields a bupivacaine MVLs composition with superior stability as compared to the product made by the

¹³ More specifically, Plaintiff explained the product’s degradation as follows: “[I]n particular, when the inventors wanted to assess stability, the property that they emphasize as being important, . . . they looked at . . . the erucic acid concentration, which . . . is a lipid degradation byproduct. So in these MVLs, you have lipids, and the main component degrades to erucic acid. And so Pacira, as they’ve laid out in the patent specification, measures the erucic acid concentration over time as an indicator of the stability of the MVL particles.” Markman Tr. at 40:2-12

prior process,” meaning there is decreased “lipid membrane degradation.” Los Dec. ¶ 4, PAC-EXPAREL 00796569.

Accordingly, the Court is not convinced that these statements, without any other reference to “batches,” refer to stability across batches as Plaintiff suggests. The Court will not read “batch-to-batch consistency” into the preamble without intrinsic or extrinsic evidence in support.¹⁴ Accordingly, the Court adopts the following construction for the ‘336 Preamble:

<u>Disputed Term</u>	<u>Adopted Construction</u>
“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” ‘336 patent, claims 1-20	“A multivesicular liposome composition encapsulating bupivacaine”

D. Shear Speed Terms

The parties dispute the construction of the terms “a high shear speed” and “a low shear speed” as part of the ‘495 Patent, and propose the following construction:

<u>Disputed Term</u>	<u>Plaintiffs’ Proposed Construction</u>	<u>Defendants’ Proposed Construction</u>
“a high shear speed” ‘495 patent, claim 9	Plain and ordinary meaning: “a high shear speed”	“a single high shear speed”
“a low shear speed” ‘495 patent, claim 13	Plain and ordinary meaning: “a low shear speed”	“a single low shear speed”

Plaintiffs propose that the terms should remain as is, and be accorded their plain and ordinary meaning. Pl. Opening Br. at 27-29. Defendants, on the other hand, argue the terms should be more limited, and construed as “a single high shear speed” and “a single low shear speed.” Def. Opening Br. at 23-27. The Court agrees with Plaintiffs.

¹⁴ As Defendant points out, the ‘348 patent, part of the same family as the ‘336 Patent, refers to “batches” that “consistently comprise an erucic acid concentration of less than 109 µg/ml after the compositions are stored at 25 °C for six months.” Def. Ex. 4, U.S. Patent No. 11,426,348, at 22:65-67. The Court agrees with Defendants that the lack of any such language in the ‘336 Patent suggests that it does not have a similar “consistency” requirement.

The Court again looks to the intrinsic record, and more specifically the claim language, first. See Vitronics, 90 F.3d at 1582. The body of the claim does not require the use several shear speeds, but the Federal Circuit has “repeatedly emphasized” the “conventional rule” that the “article ‘a’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in open-ended claims containing the transitional phrase ‘comprising.’” KCJ v. Kinetic Concepts, Inc., 223 F.3d 1351, 1356 (Fed. Cir. 2000) (collecting cases). The Kinetic Concepts Court clarified further that “[u]nless the claim is specific as to the number of elements, the article ‘a’ receives a singular interpretation only in rare circumstances when the patentee evinces a clear intent to so limit the article.” Id. Otherwise, the term “‘a,’ without more, requires at least one.” Id. In effect, “a high shear speed” and “a low sheer speed” must mean at least one shear speed.

The specification of the ‘495 Patent also explicitly defines the terms “a” and “an,” stating: “[a]s used in the specification and the appended claims, the singular forms ‘a,’ ‘an,’ ‘the’ include the plural referents unless the context clearly dictates otherwise.” ‘495 Patent 5:63-66. The Court will not depart from that definition, where the Patentee has “acted as lexicographer” and clearly defined the scope of the term. Further, neither the claims nor the specification of the ‘495 Patent express “a clear intent to so limit” the shear speed to its singular form. For example, the specification states that “in some embodiments, the high sheer speed is from about 1100 rpm to about 1200 rpm, for example, 1100 rpm, 1110 rpm, 1120 rpm, 1130 rpm, 1140 rpm, 1150 rpm, 1160 rpm, 1170 rpm, 1180 rpm, 1190 rpm, or 1200 rpm, or a range defined by any of the two preceding values.” ‘495 Patent at 7:55-59. As to low shear speed, the specification indicates that it may range from “about 450 rpm to about 510 rpm, for example, 450 rpm, 455 rpm, 460 rpm, 465 rpm, 470 rpm, 475 rpm, 480 rpm, 485 rpm, 490 rpm, 495 rpm, 500 rpm, 505 rpm, or 510 rpm, or a range defined by any of the two preceding values.” Id. at 8:12-16.

These references suggest that a POSA would understand the terms “a high shear speed” and “a low shear speed” to encompass one or more shear speeds. See Klibanov Dec. ¶ 99 (“A POSA would have understood that nothing in the ’495 patent specification indicates that ‘the context dictates’ departing from the plain and ordinary meaning of the claim language that more than a single ‘shear speed’ may be used.”).¹⁵ Consequently, Defendants’ proposed construction of “a high shear speed” as “a single high shear speed” and “a low shear speed” as “a single low shear speed” is unnecessary, and there is no construction required for the shear speed terms. Defendants’ arguments to the contrary are unavailing, and in direct conflict with Federal Circuit jurisprudence. See Baldwin Graphic Sys., Inc. v. Siebert, 512 F.3d 1338, 1342 (Fed. Cir. 2008) (The fact that “‘a’ or ‘an’ can mean ‘one or more’ is best described as a rule, rather than merely as a presumption or even a convention.”). As such, the Court adopts the following construction for the shear speed terms:

<u>Disputed Term</u>	<u>Adopted Construction</u>
“a high shear speed” ‘495 patent, claim 9	Plain and ordinary meaning: “a high shear speed”
“a low shear speed” ‘495 patent, claim 13	Plain and ordinary meaning: “a low shear speed”

E. pH Terms

Lastly, the parties dispute the construction of the pH terms that appear in the ‘495 Patent claims 1-22.

¹⁵ Dr. Yaman does not address the shear speed terms in his declaration. See generally, Yaman Dec.

<u>Disputed Term</u>	<u>Plaintiffs' Construction</u>	<u>Defendants' Construction</u>
“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is about 5.5” ‘495 patent, claim 19	Plain and ordinary meaning: “wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is approximately 5.5”	“wherein the pH of the internal aqueous chambers of the bupivacaine encapsulated MVLs in the composition is greater than or equal to 5.45 and less than 5.55”
“wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5” ‘336 patent, claims 1-20	Plain and ordinary meaning: “wherein the plurality of internal aqueous chambers of the MVLs has a pH of approximately 5.5”	“wherein the plurality of internal aqueous chambers of the MVLs has a pH is greater than or equal to 5.45 and less than 5.55”

Plaintiffs maintain that the pH terms in claim 19 of the ‘495 Patent and should be accorded their plain and ordinary meaning and construed as “approximately 5.5.” See Pl. Opening Br. at 29-30. Defendants disagree, arguing that the pH terms “about 5.5” should be construed as “greater than or equal to 5.45 and less than 5.55.” Def. Opening at 27-32. The Court agrees with Plaintiffs.

The plain and ordinary meaning of the term “about” has been recognized by the Federal Circuit as “approximately” in the context of pharmaceutical patents. Merck & Co., 395 F.3d at 1369-70; see also Biopolymer Eng'g, Inc. v. Immunocorp, No. 05-2972, 2007 WL 4562592, at *10 (D. Minn. Dec. 21, 2007) (“[d]iscerning no precise clarification of the meaning ‘about’ in the intrinsic evidence,” the Court declined to “arbitrarily construe . . . [the term by] apply[ing] general rounding principles to . . . a clearly-defined range of protein” and instead construed the term “less than about one percent, by weight, protein” as “less than approximately one percent, by weight, protein”); accord, e.g., Eiselstein v. Frank, 52 F.3d 1035, 1039 (Fed.Cir.1995) (“about” means “approximate”); Unigene Labs., Inc. v. Apotex Inc., No. 06-cv-5571, 2008 WL 3992294, at *4, *9 (S.D.N.Y. Aug. 28, 2008). The dictionary definition of “about” also means “near; close to,” or “near in time, number, degree, etc.; approximately.” See Pl. Ex. 17, Random House Websters Unabridged Dictionary, Definition of “about.”

Defendants argue their proposed construction is supported by the intrinsic record, as it is based on the inventors' disclaimers, as well as pH data presented in the specification. Def. Opening Br. at 28. The court is unconvinced. The specification explains that the difference in lysine concentration causes the internal pH of the bupivacaine MVL to increase to 5.50, as compared to an internal pH of 5.34 for the prior art. '495 Patent at 16:35-41. Similarly, the '336 Patent distinguishes the pH of "about 5.34" using the existing manufacturing process to the pH of "about 5.5" for the new process. '336 Patent at 16:43-49. Defendants argue that these are express disclaimers of a pH of 5.34. See Markman Tr. at 91:7-16 (counsel for Defendants explaining the concept of a disclaimer, and stating that a pH of 5.34 "is not about 5.5").

Defendants claim that the '727 Patent, part of the same family as the '336 and '495 Patents, also expressly disclaims an internal pH of 5.7 to 6.0. Def. Ex. 8, '727 File History, at 50. As such, Defendants argue, the inventors made clear that a pH of 5.7 is not "about 5.5," and falls outside of the range they propose. Def. Opening Br. at 30. Defendants also argue that their proposed construction is based on the "general mathematical princip[le] that a number should be rounded to its closest decimal." T.F.H. Publications, Inc. v. Doskocil Mfg. Co., No. 08-cv-4805, 2012 WL 715628, at *7 (D.N.J. Mar. 5, 2012), aff'd (June 5, 2013); see also Yaman Dec. ¶ 58 ("the term 'about 5.5' refers to a pH of greater than or equal to 5.45 and less than 5.55, consistent with standard rounding principles"). Indeed, applying mathematical rounding principles, Courts have construed claims where the term "about" precedes a number to encompass a numerical range that rounds to the stated number. See e.g., Viskase Corp. v. Am. Nat. Can Co., 261 F.3d 1316, 1320 (Fed. Cir. 2001) (affirming the district court's construction of the term "'about 0.91 g/cm' to mean densities between 0.905 and 0.914 . . . based on the standard scientific convention when a number has not been carried to the next mathematically significant figure").

Here, however, like in Biopolymer, there is no intrinsic evidence to support Defendants' construction limiting the pH range to 5.45 to 5.55. While those pH levels may fall into the range of "about 5.5," the Court "declines to arbitrarily construe 'about' through use of rounding principles." Biopolymer, 2007 WL 4562592, at *15. And with respect to Defendants' arguments regarding the distinction from prior art in the same family, those patents do not use the suggested rounding principles to limit the target pH of "about 5.34" to mean only a pH greater than or equal to 5.24 or less than 5.34.

In addition, the Court is not convinced that either "about" or "approximately" would be vague to a POSA. Defendants did not present any evidence to this effect, and "similar terms of degree are frequently used in patent claims, especially in the pharmaceutical arts." Par Pharm., Inc. v. Takeda Pharm. Co., No. 13-cv-01927, 2014 WL 2570756, at *17 (N.D. Cal. June 6, 2014) (discussing "Relative Terminology," including "about") (citing Manual of Patent Examining Procedure § 2173.05(b) (9th ed. Mar.2014)). Moreover, "[i]t is for the factfinder to decide whether a specific pH value is 'approximately' [5.45 to 5.55]." Id. (citing PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("[A]fter the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.")).

Accordingly, because the specification does not suggest any specific numerical range, and the plain and ordinary meaning has been recognized as "approximately" in this context, the Court finds the intrinsic evidence does not support a narrower construction, and therefore declines to derive a specific numerical range for the value that the term "about" modifies. The Court adopts the following construction for the pH terms:

<u>Disputed Term</u>	<u>Adopted Construction</u>
“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is about 5.5” ‘495 patent, claim 19	“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is approximately 5.5”
“wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5” ‘336 patent, claims 1-20	“wherein the plurality of internal aqueous chambers of the MVLs has a pH of approximately 5.5”

IV. CONCLUSION

For the reasons stated above, the Court adopts the following constructions:

<u>Disputed Term</u>	<u>Adopted Construction</u>
“A composition of bupivacaine encapsulated multivesicular liposomes (MVLs)” ‘495 patent, claims 1-22	“a multivesicular liposome composition encapsulating bupivacaine”
“commercial scale” ‘495 patent, claims 1-22	“a scale of manufacturing for production of a commercial product”
“prepared by a commercial scale process” ‘495 patent, claims 1-22	“prepared by a commercial scale process” is a product-by-process limitation to the extent the scale informs the claimed “composition”
“a high shear speed” ‘495 patent, claim 9	Plain and ordinary meaning: “a high shear speed”
“a low shear speed” ‘495 patent, claim 13	Plain and ordinary meaning: “a low shear speed”
“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is about 5.5” ‘495 patent, claim 19	“wherein the internal pH of the bupivacaine encapsulated MVLs in the composition is approximately 5.5”

“wherein the plurality of internal aqueous chambers of the MVLs has a pH of about 5.5”

‘336 patent, claims 1-20

“wherein the plurality of internal aqueous chambers of the MVLs has a pH of approximately 5.5”

An appropriate Order follows.

Date: June 6, 2023

/s/ Madeline Cox Arleo
Hon. Madeline Cox Arleo
UNITED STATES DISTRICT JUDGE